Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 1, 2, 9-10, 23, 27, and 32 (duplicate) are amended, and claims 8, 24-26 and 33 are canceled. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to the prejudice the prosecution of the claims prior to amendment, which claims are present in a continuation of the present application. Claims 1-7, 9-23, 27-32, and 34 are pending.

The Examiner rejected claims 1-5, 8-20 and 22-26 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,696,562. The Examiner also rejected claims 6-7 and 27-32 under 35 U.S.C. § 103(a) over the '562 patent. The Examiner further rejected claim 21 under 35 U.S.C. § 103(a) over the '562 patent in view of WO 92/20803. In addition, the Examiner rejected claims 1-8, 10-20 and 22-32 under 35 U.S.C. § 103(a) over U.S. Patent No. 5,625,049 and Koci et al. (J. Virol., 74:6173 (2000)), claim 9 under 35 U.S.C. § 103(a) over the '049 patent, Koci et al. and U.S. Patent No. 5,858,723, and claim 21 under 35 U.S.C. § 103(a) over the '049 patent, Koci et al. and WO 92/20803. These rejections, as they may be maintained with respect to the pending claims, are respectfully traversed.

The '562 patent discloses the isolation and sequencing of a turkey astrovirus (abstract). It is also disclosed that a RT-PCR assay was used to detect turkey astrovirus capsid- and polymerase-specific sequences in enteric samples including enteric samples from experimentally infected poultry and turkey poults with enteritis (Example 3).

The '562 patent further discloses that turkey astrovirus nucleic acid may be employed as a primer or probe or in vectors to express recombinant turkey astrovirus polypeptides that can be tested for antigenicity (column 7, lines 29-65 and column 8, lines 20-21). A number of different expression systems are disclosed at column 8, line 39-column 9, line 52, including prokaryotic host cells, e.g., *E. coli, Bacillus subtilis, Salmonella, Serratia* and *Pseudomonas*, and eukaryotic host cells, e.g., yeast, mammalian, and insect cells.

In addition, it is disclosed that the virus of the invention can be used to produce reagents useful to detect the virus, e.g., to produce an antibody (column 10, lines 16-21). For example, it is disclosed that a tissue or fluid sample that contains the antigen or a cell containing the antigen, is contacted with an antibody which is then contacted with an antigen, such as intact cells (column 10, lines 21-25) Other assays which employ anti-astrovirus antibodies or astrovirus antigens are disclosed at column 10, line 33-column 11, line 27) and include ELISAs, IFA, immunoblotting, and microagglutination assays. For instance, it is disclosed that an antigen can be bound to a substrate and contacted with a sample, and that antibodies specific for the antigen react with the bound antigen (column 11, lines 14-18).

While general methods that employ viral antigens and viral specific antibodies are disclosed in the '562 patent, the only data therein is for a RT-PCR assay with enteric samples. The '562 patent does not disclose or suggest identifying an animal exposed to or having antibodies specific for turkey astrovirus-2, by contacting animal blood with recombinant cells comprising an expression cassette encoding a turkey astrovirus-2 antigen or a lysate thereof, or a kit useful in that regard.

The '049 patent relates to human astrovirus-2 nucleic acid (abstract). Uses for that nucleic acid are disclosed as providing purified antigenic polypeptide fragments, primers or probes, or in vectors (column 2, lines 45-62). It is disclosed that the antigenic fragments may be isolated from the whole antigen by chemical or mechanical description, or synthesized directly (column 5, line 57-62), e.g., in a recombinant system (column 5, line 66-column 6, line 3). Numerous expression systems are disclosed at column 6, line 45-column 7, line 65. Methods of using antibodies reactive with human astrovirus-2 or human astrovirus-2 antigens are disclosed at column 8, line 42-column 10, line 14. The examples in the '049 patent describe the isolation and sequencing of human astrovirus sequences, and the comparison of those sequences with known sequences.

The '049 patent does not describe a viral protein-based assay that specifically detects animals infected with human astrovirus-2, much less turkey astrovirus-2.

WO 92/20803 discloses that five serotypes of human astrovirus have been identified (page 5, lines 33-34). The specification discloses methods for the isolation and expression of astrovirus genomic sequences. For instance, it is disclosed that astrovirus antigen can be used to identify anti-astrovirus antibodies in serum (pages 22-23), and anti-astrovirus antibodies can be used to detect astrovirus antigens (pages 24-25). It is disclosed that a human astrovirus sequences were isolated from a lambda cDNA expression library using sera from astrovirusimmunized rabbits (Examples 3, 4 and 6). Example 7 discloses how to prepare anti-human astrovirus antibodies.

WO 92/20803 does not describe a viral protein-based assay that specifically detects animals infected with human astrovirus, much less turkey astrovirus-2.

Koci et al. disclose that detection of astrovirus in most species is limited to electron microscopy and fluorescent antibody detection in cultured cells but that those methods are time intensive and vulnerable to differences in interpretation (page 79). To address the deficiencies in EM and fluorescent antibody based methods to detect turkey astrovirus, Koci et al. describe a RT-PCR based method that detected turkey astrovirus sequences in enteric samples with primers from the viral capsid and polymerase genes (abstract and page 80).

The '723 patent discloses that polypeptides with sequences corresponding to a human endogenous retrovirus (HERV-K10) are useful for diagnosing seminoma (abstract). The polypeptides may be expressed recombinantly, e.g., in *E. coli* or insect cells (Figures 2 and 4), to yield HERV-K10 antigen (column 2, lines 41-46). Antigen, e.g., gag and/or env, is discussed as useful to detect HERV-K10 specific antibodies in patients (column 2, lines 12-35). It is also disclosed that insect cells expressing HERV-K10 gag or env were mixed with sera from a variety of patients (Example 3 and Table III) and purified HERV-K10 gag or env was employed in an ELISA (Example 4). Note that the sera from healthy individuals, as well as individuals with a variety of disorders, reacted with insect cells expressing HERV-K10 gag or env.

The '723 patent does not teach or suggest assays to detect viral infection (HERV-K10 is an endogenous virus like element).

Thus, none of the cited documents alone or in combination teaches Applicant's methods or kits. Moreover, none of the cited documents provides any data on whether a turkey astrovirus protein based assay would detect antibodies to turkey astrovirus-2 in asymptomatic animals. In fact, Koci et al. teach away from protein based assays as fluorescent antibody based techniques are disclosed as laborious and subject to interpretation.

Further, nucleic acid amplification based assays, such as the RT-PCT assay disclosed in Koci et al., are generally considered very sensitive. Therefore, the cited art provides no motivation to the art worker to employ an astrovirus protein based assay.

Therefore, withdrawal of the § 102(e) and § 103(a) rejections is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to contact the Applicant's Representative at the below-listed telephone number if there are any questions regarding this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date March 10, 2006 By
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10th day of March, 2006.

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